

(A) An amount that CMS determines is actuarially sound for each uncovered month in the same continuous period of eligibility; or

(B) 1 percent of the base beneficiary premium (computed under paragraph (c) of this section) for each uncovered month in the period.

(ii) *Special rule for 2006 and 2007.* In 2006 and 2007 the penalty amount discussed in paragraph (d)(3) of this chapter equals the amount referenced in paragraph (d)(3)(i)(B) of this section unless another amount is specified in a separate issuance based on available analysis or other information as determined by the Secretary.

(e) *Decrease in monthly beneficiary premium for low-income assistance.* The monthly beneficiary premium may be eliminated or decreased in the case of a subsidy-eligible individual under § 423.780.

(f) *Special rules for fallback prescription drug plans.* The monthly beneficiary premium charged under a fallback prescription drug plan is calculated under § 423.867(a) and not under this section, except that enrollees in fallback prescription drug plans are subject to late enrollment penalties under paragraph (d)(3) of this section and fallback prescription drug plan premiums are reduced or eliminated in the case of a subsidy-eligible individual, as described in paragraph (e) of this section.

§ 423.293 Collection of monthly beneficiary premium.

(a) *General rule.* Part D sponsors must charge enrollees a consolidated monthly Part D premium equal to the sum of the Part D monthly premium for basic prescription drug coverage (if any) and the premium for supplemental coverage (if any and if the beneficiary has enrolled in such supplemental coverage). Part D sponsors must also permit each enrollee, at the enrollee's option, to make payment of premiums (if any) under this part to the sponsor using any of the methods listed in § 422.262(f) of this chapter.

(b) *Crediting of late enrollment penalty.* CMS estimates and specifies the portion of the late enrollment penalty imposed under § 423.286(d)(3) attributable to increased actuarial costs assumed by the Part D sponsor and not taken

into account through risk adjustment provided under § 423.329(b)(1) or through reinsurance payments under § 423.329(c)) as a result of the late enrollment.

(c) *Collection of late enrollment penalty—(1) Collection through withholding.* In the case of a late enrollment penalty that is collected by the government from a Part D eligible individual in the manner described in § 422.262(f)(1) of this chapter, CMS pays only the portion of the late enrollment penalty described in paragraph (b) of this section to the Part D sponsor offering the Part D plan in which the individual is enrolled.

(2) *Collection by plan.* In the case of a late enrollment penalty collected from a Part D eligible individual in a manner other than the manner described in § 422.262(f)(1) of this chapter, CMS reduces payments otherwise made to the Part D plan by an amount equal to the portion of the late enrollment penalty.

(d) *Special rule for fallback plans.* This section does not apply to fallback prescription drug plans. The fallback plans follow the requirements set forth in § 423.867(b).

Subpart G—Payments to Part D Plan Sponsors For Qualified Prescription Drug Coverage

§ 423.301 Scope.

This subpart sets forth rules for the calculation and payment of CMS direct and reinsurance subsidies for Part D plans; the application of risk corridors and risk-sharing adjustments to payments; and retroactive adjustments and reconciliations to actual enrollment and interim payments. This subpart does not apply to fallback entities or fallback prescription drug plans.

§ 423.308 Definitions and terminology.

For the purposes of this subpart, the following definitions apply—

Actually paid means that the costs must be actually incurred by the Part D sponsor and must be net of any direct or indirect remuneration (including discounts, chargebacks or rebates, cash discounts, free goods contingent on a purchase agreement, up-front payments, coupons, goods in kind, free or reduced-price services, grants, or other

price concessions or similar benefits offered to some or all purchasers) from any source (including manufacturers, pharmacies, enrollees, or any other person) that would serve to decrease the costs incurred by the Part D sponsor for the drug.

Allowable reinsurance costs means the subset of gross covered prescription drug costs actually paid that are attributable to basic prescription drug coverage for covered Part D drugs only and that are actually paid by the Part D sponsor or by (or on behalf of) an enrollee under the Part D plan. The costs for any Part D plan offering enhanced alternative coverage must be adjusted not only to exclude any costs attributable to benefits beyond basic prescription drug coverage, but also to exclude any costs determined to be attributable to increased utilization over the standard prescription drug coverage as the result of the insurance effect of enhanced alternative coverage in accordance with CMS guidelines on actuarial valuation.

Allowable risk corridor costs means the subset of actually paid costs for covered Part D drugs (not including administrative costs, but including dispensing fees) that are attributable to basic prescription drug coverage only and that are incurred and actually paid by the Part D sponsor under the Part D plan. Costs must be based upon imposition of the maximum amount of copayments permitted under § 423.782. The costs for any Part D plan offering enhanced alternative coverage must be adjusted not only to exclude any costs attributable to benefits beyond basic prescription drug coverage, but also to exclude any prescription drug coverage costs determined to be attributable to increased utilization over standard prescription drug coverage as the result of the insurance effect of enhanced alternative coverage in accordance with CMS guidelines on actuarial valuation.

Coverage year means a calendar year in which covered Part D drugs are dispensed if the claim for those drugs (and payment on the claim) is made not later than 3 months after the end of the year.

Gross covered prescription drug costs means those actually paid costs incurred under a Part D plan, excluding

administrative costs, but including dispensing fees during the coverage year and costs relating to the deductible. They equal—

(1) All reimbursement paid by a Part D sponsor to a pharmacy (or other intermediary) or to indemnify an enrollee when the reimbursement is associated with an enrollee obtaining drugs under the Part D plan; plus

(2) All amounts paid under the Part D plan by or on behalf of an enrollee (such as the deductible, coinsurance, cost-sharing, or amounts between the initial coverage limit and the out-of-pocket threshold) in order to obtain drugs covered under the Part D plan. These costs are determined regardless of whether the coverage under the plan exceeds basic prescription drug coverage.

Target amount for any Part D plan equals the total amount of payments (from both CMS and by or on behalf of enrollees) to that plan for the coverage year for all standardized bid amounts as risk adjusted under § 423.329(b)(1), less the administrative expenses (including return on investment) assumed in the standardized bids.

§ 423.315 General payment provisions.

(a) *Source of payments.* CMS payments under this section are made from the Medicare Prescription Drug Account.

(b) *Monthly payments.* CMS provides a direct subsidy in the form of advance monthly payments equal to the Part D plan's standardized bid, risk adjusted for health status as provided in § 423.329(b), minus the monthly beneficiary premium as determined in § 423.286.

(c) *Reinsurance subsidies.* CMS provides reinsurance subsidy payments described in § 423.329(c) on a monthly basis during a year based on either estimated or incurred allowable reinsurance costs as provided under § 423.329(c)(2)(i), and final reconciliation to actual allowable reinsurance costs as provided in § 423.343(c).

(d) *Low-income subsidies.* CMS makes payments for premium and cost sharing subsidies, including additional coverage above the initial coverage limit, on behalf of certain subsidy-eligible individuals as provided in § 423.780 and § 423.782. CMS provides low-income